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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/985,742	12/04/92	COMAI	L CGNE-62-1(1)
			EXAMINER
			MOODY, P
			ART UNIT
			PAPER NUMBER
			1804
			19

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18M1

DATE MAILED: 03/04/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4 December 1992 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892. 1061
- ☐ Notice re Patent Drawing, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449. 343
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

- ☒ Claims 20-42 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☒ Claims 1-19 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 20-42 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received.
☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5 Claims 20-42 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Recited construct elements of claims 20-42 are inadequate to achieve the stated result. For example, 3' termination sequences are missing and elements are not operably joined in claims 20, 29-32, 37 and 39-42. Furthermore, claims 37-38 appear to omit method steps i.e. "having" suggests a previous step and "whereby" phrase does not define a phenotype modification; indeed, no recited element achieves phenotype modification. Method claims 15 39-40 fail to recite any steps and do not set forth actual methods. Method claims 41-42 each recite a single step which fails to achieve the transcription asserted in the preamble.

20 "Untranslated end" (claim 22) is vague and indefinite as 3' transcription termination regions are flanking regions not ends. Claims 24-26 are vague and indefinite as it is unclear which direction is "upstream" for DNA which is double stranded and it is not clear what else "at least approximately" includes that was not already embraced by the phrase, "at least".

25 Claims 29-32 fail to distinctly claim the invention as a "CaMV 35S promoter construct" cannot be comprised of itself and still be a construct (as in claims 29 and 32 for example) e.g., a construct would have chimeric components such as enhancers, CAAT boxes, TATA boxes and ribosome binding sites. Also the term

"second DNA" in these claims implies that there is a first DNA but the claims do not presently describe a first DNA which leads to a confusing antecedent basis for the sequences of interest in claim 30. Claim 31 lacks antecedent basis for "CaMV 35S promoter cassette" and it is not possible for promoters to be "further comprised" of transcript termination regions (claims 31-32). Claim 32 lacks antecedent basis for "said transcript termination region of said figwort 34S promoter construct".

Apparently "promoter" has been used in this disclosure in a non-standard way to refer to the entire 5' untranslated flanking sequence (composed of TATA box and enhancer) rather than to the polymerase binding site (TATA box) which promotes transcription. Consequently, "promoter" as used here already contains an untranslated leader sequence and cannot be said to "further comprise" a leader sequence as in claims 33-34. Claims 29-32 and 41-42 are also confusing because there is no apparent interaction or relationship or structural orientation or cooperation between constructs which have CaMV promoters and constructs which have FMV promoters.

Claims 39-42 are vague and indefinite in that it is not clear what constitutes a "method of providing" and "having" appears to refer to an act not set forth in these claims. It is unclear what constitutes "expression" in claim 40. Claim 41 is vague and indefinite as it is not clear what a "similar level of transcription" encompasses especially where, as here, the "CaMV

35S promoter" is undefined (i.e. there are numerous subsets and arrangements of sequences that have various activities) and the "different promoter" is unspecified. The negative limitation in claim 42 renders the claim indefinite and fails to distinctly set forth the invention e.g., it is not clear what "CaMV 35S-like" embraces and claim 42 depends from a cancelled claim.

Claims 20-42 remain rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, 23-26, 32, 37, and 39-40 refer to a "figwort 34S promoter" but the disclosure describes a figwort mosaic virus 34S promoter. A figwort is a type of plant, thus the claim does not point out the subject matter applicant regards as the invention and the claimed invention is not described in the disclosure.

The chimeric promoter of claims 39-40 lacks support in that the disclosure fails to describe a "caulimovirus promoter comprising a figwort 34S promoter". Claim 42 is vague and indefinite as to what transcription levels would be considered "CaMV 35S-like"; the specification sheds no light on the issue.

Claim 41 remains rejected under 35 USC § 112, first paragraph, as the disclosure is enabling only for claims limited to the disclosed FMV 34S promoter. Various activities of various CaMV 35S constructs in various tissues under various conditions render a "different promoter having" similar activity not commensurate in scope with the disclosure as filed. See MPEP §§ 706.03(n) and 706.03(z).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-40 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Shepherd et al where the sequence of interest is an FMV gene.

Claims 20-21, 23-27, and 33-34 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Richins et al which disclosed cloned XbaI fragments joined in a 5' to 3' direction to β -galactosidase.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 20-42 remain rejected under 35 U.S.C. § 103 as being unpatentable over Shah et al and Sanders et al taken with Richins

et al and Shepherd et al as applied in the last office action and repeated herein.

5 Each of the primary references disclosed all features of the present invention (including constructs with genes of interest controlled by two different strong, constitutive promoters one of which was a CaMV 35S promoter) but did not identify FMV 34S as an alternative viral promoter. Richins et al disclosed the FMV 34S promoter sequence and taught that it was analogous to CaMV 35S in position, structure, and function and, likewise, expected to have similar strong expression characteristics. This was echoed by Shepherd et al which taught that FMV was as amenable to cloning manipulation as CaMV. Shepherd et al described the broad host range and high titer achievable with FMV in plant host cells and also compared CaMV and FMV promoters. At the time this invention was made, it was obvious to one of ordinary skill in the art to modify the primary references with the teachings of the secondary references in order to obtain high levels of expression of genes of interest in host plant cells with yet another strong viral promoter source. The extensive comparative analogy drawn with CaMV would have led one of ordinary skill in the art to have reasonably expected to obtain high levels of constitutive expression with analogous FMV promoters. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

No claim was allowed.

30 This is a continuation of applicant's earlier application S.N. 07/431429. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

Serial No. 07/985742
Art Unit 1804

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5 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL
ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS
ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS
OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION
IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED
STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE
ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE
PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE
MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE
10 STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM
THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed
to P. Moody (nee Rhodes) at telephone number (703) 308-0196.

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ppm
P. Moody
March 2, 1993

20 DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

25 *David T. Fox*

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